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10/626,459	07/22/2003	Shuichi Mizuno	3831.03	2554

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HANA VERNY
PETERS, VERNY, JONES & SCHMITT, L.L.P.
SUITE 230
425 SHIRMAN AVENUE
PALO ALTO, CA 94306

EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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10/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/626,459

Applicant(s)

MIZUNO ET AL.

Examiner

David M. Naff

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

An amendment of 7/23/08 amended claims 38-40 and canceled claim 48. Claims 1-37 have been previously canceled.

Claims examined on the merits are 38-47, which are all claims in the application.

5 ***Claim Objections***

Claims 41-46 are objected to because of the following informalities: the claims are identified as ("new") but should be identified as "(previously presented)" since the claims were new in the previous amendment of 11/5/07. Appropriate correction is required.

Claim Rejections - 35 USC § 112

10 The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15 Claims 38-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the
20 claimed invention.

In claim 38, step h), the specification fails to recite and support "growth and maturing of said chondrocytes or stem cells", "integration of said construct seeded with said chondrocytes or stem cells into a native cartilage", and "both degraded within said three months" (last line). Maturing of chondrocytes or stem cells is not described. The growth and maturing of cartilage
25 occurs (paragraph 0110 of published specification). The specification fails to describe seeding of the construct and integration of the seeded construct into native cartilage. The specification describes seeding of the support matrix and integration of new cartilage into native cartilage

(paragraphs 0031, 0110 and 0354). Description is not found of both the support matrix and polyethylene glycol cross-linked with methylated collagen degrading within three months. The specification describes the TRGH subsequently degrading after neo-cartilage is integrated into existing cartilage (paragraph 0173). Integration of the neo-cartilage would occur within three months since overgrowth of superficial cartilage occurs in about two-three months (paragraph 0110). While paragraph 0110 recites "about two-three months when the sealant is itself degraded", this means the sealant is degraded after the two-three months since paragraph 0173 discloses TRGH subsequently degrading after the integration of the neo-cartilage.

Support is not found in the specification for the superficial cartilage layer constituting a substitute synovial membrane as required in claim 47 when the superficial cartilage layer is a layer of squamous-like flattened superficial zone chondrocytes covering as required in claim 38 (lines 12-14 of step h)). The specification is unclear as to the relationship of the substitute synovial membrane to the layer of squamous-like flattened superficial zone chondrocytes covering. The specification fails to describe how the two superficial cartilage layers relate to each other. Are the two superficial cartilage layers alternative layers or is one layer a species of the other layer or are both layers inherently the same?

Response to Arguments

Amendments to claims have overcome the lack of support noted in the previous office action, however other claim amendments to claims do not have support in the specification for reasons set forth above.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 6 of step f) of claim 38, reciting "chondrocytes" is confusing since the claim
5 previously recites "chondrocytes or stem cells". It is suggested "chondrocytes" be changed to --- said chondrocytes or stem cells --- to be consistent with the previous recitation and be clear that the chondrocytes or stem cells are those previously required.

Bridging lines 6 and 7 of step h), "maturing of said chondrocytes or stem cells" is unclear as to physical phenomena that constitutes maturing of said chondrocytes or stem cells. How
10 maturing differs from growth of the cells is uncertain.

Bridging lines 7 and 8 of step h), "said construct seeded with said chondrocytes or stem cells" does not have clear antecedent basis. In previous step e), the support matrix is seeded, and in step f) the seeded support matrix is subjected to conditions to produce the construct.

Bridging lines 7 and 8 of step h), "integration of said construct" is confusing since the
15 specification discloses new cartilage integrating, and not the construct integrating.

Bridging lines 10 and 11 of step h), requiring a superficial cartilage layer to overgrow the construct is confusing since polyethylene glycol cross-linked with methylated collagen has been deposited over the construct in lines 1-2 of step h). Therefore, the superficial cartilage layer should be required to overgrow the polyethylene glycol cross-linked with methylated collagen
20 deposited over the construct.

In line 13 of step h), "squamous-like" is uncertain as to meaning and scope. Being "like" squamous is relative and subjective, and depends on individual interpretation of how similar to squamous is like squamous.

In line 14 of step h), "flattened superficial zone chondrocytes covering a layer" is unclear as to meaning and scope. The relationship of the chondrocytes to the flattened superficial zone, and the material flattened is unclear. Are the chondrocytes, the zone or both flattened? How a zone can be flattened is uncertain since a zone is not a physical material? Additionally,

- 5 "flattened superficial zone chondrocytes" is confusing since the claim previously recites "said chondrocytes or stem cells", and relationship of the flattened superficial zone chondrocytes to the chondrocytes or stem cells previously required is unclear.

Bridging lines 12 and 13 of step h), "cartilage layer is an outermost layer" is unclear how this further defines the cartilage layer in addition to forming a superficial cartilage layer that
10 overgrows the construct as required in lines 9-11. If the superficial cartilage layer overgrows the construct, the superficial cartilage layer is inherently an outermost layer.

In lines 17-19 of step h), requiring the support matrix and polyethylene glycol cross-linked with methylated collagen to both degrade in three months is confusing since lines 6-9 require integration of the seeded construct into native cartilage within three months. The polymer matrix
15 forms the construct, and if both the support matrix and sealant (polyethylene glycol cross-linked with methylated collagen) degrade within three months, there will be no construct to undergo integration within three months. Additionally, if the sealant degrades within three months, there will be no sealant for the superficial cartilage layer to overgrow within three months as required in lines 6-11. It is suggested the added portion by amendment to step h) from "a" in line 6 to "in"
20 in line 9, and lines 12-19 be deleted.

Claim 47 is unclear as to the relationship of the superficial cartilage layer that constitutes a substitute synovial membrane to the superficial cartilage layer that forms a layer of squamous-like flattened superficial zone chondrocytes in line 13-14 of step h). How these two superficial cartilage layers differ and relate to each other is unclear.

In line 2 of claim 47, --- forming --- should be inserted after "constitutes" to be consistent with "formation" previously recited.

Response to Arguments

Amendments to claims have overcome indefiniteness noted in the previous office action, however other amendments to claims have introduced additional indefiniteness in the claims for reasons set forth above.

Conclusion

The claims are free of the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/
Primary Examiner, Art Unit 1657

DMN
10/10/08